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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,797	10/16/2003	Joel E. Bernstein	812540605047	7930

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EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,797	BERNSTEIN, JOEL E.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diminishing painful disorders, does not reasonably provide enablement for preventing painful disorders and treat other chronic pain, as claimed by Applicant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.
The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is directed to a method of providing diminishment or prevention of painful disorders, comprising topically or intranasally administering a composition comprising civamide and a vehicle.

(2) The state of the prior art

The state of the art is what prior art knows about the invention. EP 0506658 provides methods to treat painful, inflammatory or allergic disorders comprising topically administering civamide (See p. 2). There is no known art, wherein a certain composition is administered to successfully prevent painful disorders before their occurrence.

(3) The relative skill of those in the art

The relative skill of the artisan having a Ph.D. in the biochemical arts is high.

(4) The predictability or unpredictability of the art

The unpredictability of painful disorders is very high. Painful disorders may be caused by a variety of factors and medical conditions. In the instant invention the predictability is very low, and consequently there is the need for a higher level of directions and guidance by Applicant. However, the amount of direction and guidance provided in the specification is limited to the treatment of painful disorders, such as headache and arthritis. No guidance is provided by Applicant regarding preventing painful disorders or treating other kinds of chronic pain.

(5) The breadth of the claims

The breadth of the claims is acceptable.

(6) The amount of direction or guidance presented

The amount of direction and guidance provided by Applicant is limited to treatment of headache and arthritis. There is no evidence in the specification that established correlation between the experiments and the claimed utility of preventing painful disorders and treating other kinds of chronic pain.

(7) The presence or absence of working examples

The working examples present no data on the effect of the compositions of the invention on the prevention of painful disorders and treatment of other kinds of chronic pain.

(8) The quantity of experimentation necessary

The effect of the compositions of the invention on the possible prevention of painful disorders and treatment of other chronic pain cannot be predicted a priori but must be determined from the case to case by painstaking experimental study in vivo. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine a possible preventive effect of the method claimed in the instant application.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 3 and 5, the phrase "other types of chronic pain" renders the claims indefinite, because it is not clear what chronic pain is treated by the method of the invention, and the specification does not provide any description of other chronic pain treated by the method of the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (EP 0506658).

The European patent provides methods to treat painful, inflammatory or allergic disorders comprising administering formulations of civamide in a vehicle to the skin or mucosal membranes, including nasal solutions, and teaches that the amount of civamide is 0.001-1.0% (See col. 2, lines 1-49). Thus, the patent provides a method as claimed in claim1 of the instant

application. With regard to the limitation in claim 1, of providing a long-lasting diminishment of painful disorders, and the limitation in claims 2-5, that the composition is administered over a period of five to fourteen days, or two weeks to several months and then discontinued, the European patent teaches that the formulations of the invention were administered for 2 weeks (See Example 4), and 4 weeks (See Example 5), and then discontinued. Thus, the patent provides a length of administration period as claimed by Applicant. The long-lasting effect claimed by Applicant is inherent to the composition administered in the method of the invention. With respect to the painful disorders recited in instant claims 3 and 5, the European patent teaches a method for the treatment of neuropathies and arthritis (See col. 3, lines 5-11), as claimed by Applicant.

The method disclosed by Bernstein et al. meet the limitations of claims 1-5 of the instant application, as the patent contemplates methods of treatment of painful disorders comprising administering civamide. Thus, the patent anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brand (EP 0149545).

The European Patent discloses methods of providing analgesia and treat inflammation associated with muscular-skeletal disorders comprising topically administering compositions comprising a capsaicinoid and a carrier (See p. 13, line 24 to p. 14, line 29). With regard to claims 1-5, Brand does not specifically include civamide in the methods of the invention, however, the patent teaches that civamide is known as an analgesic (See p. 3, lines 14-15). Brand is also deficient in the sense, that the patent does not specifically disclose the amount of caipsaicinoid administered in the method of the invention, however, the patent teaches that the amount depends on the relative strength of the compound and the severity of the pain being treated (See p. 10, lines 29-35). Thus, one of ordinary skill in the art would have been able to determine the optimal amount of civamide by routine experimentation and clinical trials. With regard to the long-term effect claimed by Applicant in claims 1-5, Brand teaches that capsaicinoids retain effectiveness over unusually long time periods (See p. 6, lines 9-18). Thus, it would have been obvious to one of ordinary skill in the art to discontinue the administration of civanil after a few days or couple of weeks, depending on the severity of the pain, with the expectation that the effect of civanil would be long lasting. With regard to the diseases claimed in claims 3 and 5, the method disclosed by the prior art is aimed at treating pain and inflammation of the joints (See p. 14, lines 19-29). Thus the patent contemplates neuralgia and arthritis, which is an inflammation of the joints.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Brand to device methods of treating painful disorders, comprising administering civamide. The expected result would have been a successful method of treatment. Because of the teachings of Brand, that civamide is known as an analgesic,

and capsaicinoids provide a long lasting effect in the treatment of painful disorders, one of ordinary skill in the art would have a reasonable expectation that the methods claimed in the instant application would be successful in treating pain. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318 (571-272-0592 after February 3, 2004). The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927 (571-272-0602 after February 3, 2004). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

January 25, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600